

Appl. No. 09/580,819  
Atty. Docket No. 7606R  
Amdt. dated 12/16/2003  
Reply to Office Action of 10/17/2003  
Customer No. 27752

### REMARKS

All claims are rejected under 35 USC §102 as anticipated by Allen et al. (6,334,856) and/or Gerstel et al. (3,964,482) or are obvious in view of Allen et al. further in view of Reed et al. (5,676,850). Allen et al. discloses microneedles having a circular cross-section and a conical or hollow frusto-conical shape. Likewise, Gerstel et al. teaches a drug delivery device having projections of conical or cylindrical cross-sections. Reed et al. teaches a plurality of barbs. The barbs generally have diametrically opposed re-entrant segments, curving back towards the proximal end of the barb and the substrate.

The instant claims, as amended hereunder, are amended to recite a sharp edge running parallel to the longitudinal axis of the projection. Basis for this amendment is found in the specification (43:5-45:12 and Figs. 32-34). No new matter is added. The sharp edge, extending substantially parallel to the longitudinal axis acts as a blade, allowing easier and more efficient penetration of the stratum corneum. Further, such a geometry allows for more a cleaner incision in the stratum corneum, resulting in less damage thereto.

The instant amendment overcomes the anticipation rejections over Allen et al. and Gerstel et al. Neither reference teaches a sharp edge running substantially along the longitudinal axis. Furthermore, combining Reed et al. does not produce the claimed invention. Reed et al. teaches barbs angled back towards the substrate, rather than running along the longitudinal edge of the projection. The Reed et al. barbs would inhibit – not enhance – penetration of the projection into the stratum corneum. Accordingly, Reed et al. does not teach or suggest the claimed invention.

Four dependent claims have been added to further specify the geometry of the claimed projection. Basis is found in the specification, as set forth above. No new matter is added with the dependent claims.

Applicants respectfully request the foregoing amendments be entered and the Examiner reconsider and allow all claims remaining in the application.

Respectfully submitted,

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